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EXAMINER	
YANG, ANDREW GUS	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,825	ALFANO ET AL.	
	Examiner	Art Unit	
	ANDREW YANG	2628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 18 is directed towards a computer program not stored on a computer readable medium. Computer programs claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical "things." They are neither computer components nor statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035. Accordingly, it is important to distinguish claims that define descriptive material per se from claims that define statutory inventions. See MPEP 2106.

Claim 20 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 20 is directed towards a phantom which is nonfunctional descriptive material. Nonfunctional descriptive material does not

constitute a statutory process, machine, manufacture, or composition of matter and is rejected under 35 U.S.C. 101. Certain types of descriptive material, such as music, literature, art, photographs, and mere arrangements or compilations of facts or data, without any functional interrelationship is not a process, machine, manufacture, or composition of matter. See MPEP 2106.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 17 discloses an apparatus for processing images but there is no disclosure in the specification as to how to make the apparatus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-8, 12-13, and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. ("Fabrication of Dynamic Optical Head Phantoms from an MRI Head Model").

With respect to claim 1, Takahashi et al. disclose: a process for preparing three-dimensional digital images for realising a biomorphic multicompartmental phantom, representing at least one organ and/or at least one system belonging to a living being (page 513, paragraph 1, lines 1-3, paragraph 3, lines 1-3, paragraph 4, line 1), comprising a first phase A.1 of acquisition of images or "sequences" of the organ or of the system belonging to the living being, according to predefined acquisition parameters (page 513, paragraph 1, lines 5-7), forming a volumetric image defined by voxels (page 515, paragraph 1, the 3-D shape of the five tissue types discloses a volumetric image by voxels), further comprising a phase A.2 of identification of tissues and/or tissue liquids and a phase B of selection of at least three of said tissues and/or tissue liquids (page 514, paragraph 1, page 516, table 1), the process being characterised in that it comprises the following phases: C.1 verifying the adjacency of the voxels, so that each tissue or tissue liquid defines a connected volume representing the tissue or tissue liquid itself (page 514, paragraph 1, page 515, paragraph 1, the determination of the outer 3-D shapes of the five tissue types discloses verifying the adjacency of the voxels); C.3 preparing an image presenting the surfaces of the volumes defined in phase C.1 according to the following sub-phases: C.3.2 determining a number of surfaces equal to the number of tissues, such that they result internal to one another, even if partially tangent, said surfaces being the convolution of the surfaces of one or

more volumes defined in phase C.1 (page 514, paragraph 1, the five tissue types), said surfaces giving, by addition or subtraction, all the surfaces corresponding to the tissues or tissue liquids selected in phase B (page 515, lines 3-5); C.3.3 assigning a thickness to said surfaces, so that in the portions wherein two or more surfaces are tangent to one another the thickness is assigned to only one surface, the set of said thicknesses forming a connected volume (page 513, third paragraph, lines 9-10).

With respect to claim 6, Takahashi et al. disclose the process according to claim 1, characterised in that it carries out, before phase C.3.2, the following phase: C.3.1 transforming the vector representation of the voxels into the vector representation of the surfaces separating the several tissues (page 514, lines 1-4, page 515, lines 2-4, the outer 3-D shapes of the five tissue types are the surface representations of the tissues).

With respect to claim 7, Takahashi et al. disclose the process according to claim 1, characterised in that the organ of the living being, the images of which are acquired in phase A.1, is the brain of a superior primate (page 513, paragraph 4, line 1).

With respect to claim 8, Takahashi et al. disclose the process according to claim 7, characterised in that the organ of the living being, the images of which are acquired in phase A.1, is the brain of a human being (page 513, paragraph 4, line 1).

With respect to claim 12, Takahashi et al. disclose the process according to claim 7, characterised in that said at least three tissues or tissue liquids selected in phase B are the grey matter, the white matter and the encephalorachidian liquid (page 513, lines 2-3).

With respect to claim 13, Takahashi et al. disclose the process according to claim 7, characterised in that during phase C.3.2 a first surface containing the white matter plus the grey matter, a second surface containing only the grey matter, and a third surface representing the cranium surface are selected, the volume containing the encephalorachidian liquid and the volume containing only the white matter being obtained by subtraction between said surfaces (page 517, paragraph 3, page 518, page 519, paragraphs 1-3, Figs. 6-3, 6-6, and 6-7).

With respect to claim 16, Takahashi et al. disclose the process according to claim 1, characterised in that the image obtained from phase C.3.3 is modified so as to create channels entering the compartments/chambers corresponding to the selected tissues or tissue liquids, said channels being used for filling and emptying the phantom (page 519, paragraph 4, Fig 6-7).

With respect to claim 17, Takahashi et al. disclose an apparatus for processing images starting from images of an organ of a living being (page 513, paragraph 2, line 1, page 515, line 1, prototyping machine), characterised in that it automatically carries out in a configurable mode phases A.1 and A.2 according to claim 1, and also phases B and C (see rationale for rejection of claim 1).

With respect to claims 18-19, Takahashi et al. disclose a computer program (page 515, line 1, computer of the prototyping machine reads a computer program) characterised in that it comprises code means adapted to execute, when running on a computer, the process according to claim 1 (see rationale for rejection of claim 1) and a

memory medium readable by a computer, storing a program, characterised in that the program is the computer program according to claim 18.

With respect to claim 20, Takahashi et al. disclose a biomorphic multicompartmental phantom, suitable for multianalytical examinations, characterised in that it is produced through a rapid prototyping device using the images processed according to the process according to claim 1 (see rationale for rejection of claim 1), the surfaces having thickness being made of solid synthetic matter (page 516, paragraph 3) and the volumes representing the various tissues and/or tissue liquids being left empty and so forming several fillable compartments (page 517, paragraph 1).

With respect to claim 21, Takahashi et al. disclose the phantom according to claim 20, characterised in that the rapid prototyping device is a stereolithographer (page 513, paragraph 1, lines 5-7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-3, 5, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. ("Fabrication of Dynamic Optical Head Phantoms from an MRI Head Model") in view of Shen et al. ("Segmentation of 2D and 3D Images Through a Hierarchical Clustering Based on Region Modeling").

With respect to claim 2, Takahashi et al. disclose the process of claim 1. However, Takahashi et al. do not expressly disclose the process is characterised in that phase C.1 comprises the following sub-phases: C.1.1 selecting a voxel from the set of voxels forming the whole acquired volume; C.1.2 comparing the selected voxel with a neighbourhood of six voxels which are connected to it through one face; C.1.3 if another voxel of the same type (belonging to the same tissue or tissue liquid) does exist in said neighbourhood, examining the neighbourhood of this one, and so on recursively; C.1.4 if during phase C.1.3 an island of one or more connected voxels of the type selected in phase C.1.1 is identified, which is surrounded by one or more volumes of voxels of other types, carrying out the following sub-phase: C.1.4.1 if said island has size smaller than a predetermined threshold, assigning the voxels of said island to the tissue which is most represented in a region including the island.

Shen et al., who also deal with computer graphics, disclose a process characterised in that phase C.1 comprises the following sub-phases: C.1.1 selecting a voxel from the set of voxels forming the whole acquired volume (page 1298, paragraph 1); C.1.2 comparing the selected voxel with a neighbourhood of six voxels which are connected to it through one face (page 1298, paragraph 1, in formula (8) in which p = 6, disparity of voxels described in sections 3.2.1-3.2.3); C.1.3 if another voxel of the same type (belonging to the same tissue or tissue liquid) does exist in said neighbourhood, examining the neighbourhood of this one, and so on recursively (page 1298, column 2, paragraphs 1-2, page 1300, section 3.2.4); C.1.4 if during phase C.1.3 an island of one or more connected voxels of the type selected in phase C.1.1 is identified, which is

surrounded by one or more volumes of voxels of other types, carrying out the following sub-phase: C.1.4.1 if said island has size smaller than a predetermined threshold, assigning the voxels of said island to the tissue which is most represented in a region including the island (page 1300, column 2, lines 6-9).

Takahashi et al. and Shen et al. are in the same field of endeavor, namely computer graphics.

At the time of the invention, it would have been obvious to one skilled in the art to combine the method of determining 3D brain volumes as taught by Shen et al. in the Takahashi et al. reference, because this would facilitate the process of automatic brain segmentation by determining the correct voxels and generate the correct segmented tissue surfaces.

With respect to claim 3, Takahashi et al. disclose the process according to claim 1. However, Takahashi et al. does not expressly disclose the process is characterised in that it further comprises, after phase C.1.4.1, a phase C.1.4.2 wherein, according to the method of the previous phases, the existence of islands having size larger than said threshold is verified and, in the positive, one of the following sub-phases is alternatively carried out: reassign the island to one of said tissues or tissue liquids; connecting the island, through a channel, to one of said tissues or tissue liquids.

Shen et al., who also deal with computer graphics, disclose a process characterised in that it further comprises, after phase C.1.4.1, a phase C.1.4.2 wherein, according to the method of the previous phases, the existence of islands having size larger than said threshold is verified and, in the positive (page 1304, column 2, lines 11-

23, merging case), one of the following sub-phases is alternatively carried out: reassign the island to one of said tissues or tissue liquids; connecting the island, through a channel, to one of said tissues or tissue liquids (page 1298, column 1, paragraph 4).

Takahashi et al. and Shen et al. are in the same field of endeavor, namely computer graphics.

At the time of the invention, it would have been obvious to one skilled in the art to combine the method of determining 3D brain volumes as taught by Shen et al. in the Takahashi et al. reference, because this would facilitate the process of automatic brain segmentation by determining the correct voxels and generate the correct segmented tissue surfaces.

With respect to claim 5, Takahashi et al. disclose the process according to claim 1. However, Takahashi et al. do not expressly disclose the process is characterised in that phase B further comprises the following phases: B.1 eliminating all the tissues except a predetermined set of tissues; B.2 filling the holes by assigning the corresponding voxels to at least one tissue of the predetermined set.

Shen et al., who also deal with computer graphics, disclose a process characterised in that phase B further comprises the following phases: B.1 eliminating all the tissues except a predetermined set of tissues (page 1304, column 1, lines 14-17); B.2 filling the holes by assigning the corresponding voxels to at least one tissue of the predetermined set (page 1300, column 2, lines 6-10).

Takahashi et al. and Shen et al. are in the same field of endeavor, namely computer graphics.

At the time of the invention, it would have been obvious to one skilled in the art to combine the method of determining 3D brain volumes as taught by Shen et al. in the Takahashi et al. reference, because this would facilitate the process of automatic brain segmentation by determining the correct voxels and generate the correct segmented tissue surfaces.

With respect to claim 9, Takahashi et al. disclose the process according to claim 7, characterised in that during phase A.1 it is acquired a number of axial images ranging from 60 to 300 (page 513, paragraph 4, lines 5-10, 249 slices) and with spacing from a centre to another one ranging from 0.5 to 2 mm (page 513, paragraph 4, lines 5-10, spacing 0.8 mm), said images representing axial sections of the brain. However, Takahashi et al. disclose layers having a thickness of 0.2 mm (page 513, paragraph 4, lines 5-10) instead of layers having thickness ranging from 1 to 4 mm.

At the time of the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify Takahashi et al. to use a use similar design parameters because Applicant has not disclosed that using such parameters provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with using said parameters because the parameters are only chosen as similar design parameters.

Therefore, it would have been an obvious matter of design choice to modify Takahashi et al. to obtain the invention as specified in claim 9.

With respect to claim 10, Takahashi et al. disclose the process according to claim 9, characterised in that said images which are acquired are MRI images (page 513, paragraph 3, lines 1-3).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. ("Fabrication of Dynamic Optical Head Phantoms from an MRI Head Model") in view of Ng (U.S. Patent No. 6,856,314).

With respect to claim 4, Takahashi et al. disclose the process according to claim 1. However, Takahashi et al. do not expressly disclose the process is characterised in that it further comprises a phase C.2 of smoothing the images in the three dimensions.

Ng, who also deals with computer graphics, discloses a method of 3D image smoothing (column 16, lines 50-55).

Takahashi et al. and Ng are in the same field of endeavor, namely computer graphics.

At the time of the invention, it would have been obvious to one skilled in the art to combine the method of 3D image smoothing as taught by Ng in the Takahashi et al. reference because this would significantly enhance the 3D image information that would be displayed (column 16, lines 53-55 of Ng).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. ("Fabrication of Dynamic Optical Head Phantoms from an MRI Head Model") in view of Cuisenaire ("The Physics of T1- and T2-weighted MRI").

With respect to claim 11, Takahashi et al. disclose the process according to claim 9. However, Takahashi et al. do not expressly disclose the process is characterised in that the T1-w and PD-T2-w sequences are acquired for each localization of layer.

Cuisenaire, who also deals with computer graphics, discloses acquiring T1-, T2-, and PD weighted images (page 2).

Takahashi et al. and Cuisenaire are in the same field of endeavor, namely computer graphics.

At the time of the invention, it would have been obvious to combine the method of acquiring T1-, T2-, and PD weighted images as taught by Cuisenaire with the Takahashi et al. reference because this would provide multiple channels to observe the same anatomy (page 2 of Cuisenaire).

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. ("Fabrication of Dynamic Optical Head Phantoms from an MRI Head Model") in view of Gibson et al. (U.S. Patent No. 6,362,821).

With respect to claims 14-15, Takahashi et al. disclose the process of claim 7 and 14, respectively. However Takahashi et al. do not expressly disclose the process is characterised in that phase B has a phase B.3 in which the definition of the tissues in the images under processing is corrected and in that in phase B.3 the definition and the form of the basal ganglia of the brain are improved.

Gibson et al., who also deal with computer graphics, disclose a method for performing structural correction of a segmented structure (column 3, lines 51-53). Such editing would improve image quality of a segmented brain structure.

Takahashi et al. and Gibson et al. are in the same field of endeavor, namely computer graphics.

At the time of the invention, it would have been obvious to one skilled in the art to combine the method of correcting a segmented structure as taught by Gibson et al. with the Takahashi et al. reference because this would all for highlighting regions of interest and specifying labels for contained voxels (column 3, lines 53-55 of Gibson et al.).

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. ("Fabrication of Dynamic Optical Head Phantoms from an MRI Head Model")

With respect to claims 22-24, Takahashi et al. disclose the phantom of claim 20, characterised in that said compartments are filled with liquid (page 517, lines 1-8). However, Takahashi et al. do not expressly disclose the phantom is characterised in that said compartments are filled with water or solutions containing radioisotopes, for its use in Nuclear Medicine, characterised in that said compartments are filled with solutions of contrast media or paramagnetic ions, for use in Computerised Axial Tomography and Magnetic Resonance, and characterised in that said compartments are filled with aqueous solutions of nickel and/or manganese and/or gadolinium.

At the time of the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify Takahashi et al. to use a use similar liquids because Applicant has not disclosed that using such liquids provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to

perform equally well with using said liquids or solutions because the solutions are only selected depending on optical properties, i.e. scattering and absorption coefficients depending on the body of interest.

Therefore, it would have been an obvious matter of design choice to modify Takahashi et al. to obtain the invention as specified in claims 22-24.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,535,623 to Tannenbaum et al. for a method of acquiring MRI images and performing segmentation

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-5514. The examiner can normally be reached on 8:30-5 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ulka Chauhan can be reached on (571) 272-7782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ulka Chauhan/
Supervisory Patent Examiner, Art Unit 2628

AGY

8/1/08